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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,439	06/16/2005	Ennio Ongini	026220-00066	3232
4372 7590 06/13/2007 ARENT FOX PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER YOUNG, SHAWQUIA	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 06/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,439	Applicant(s) ONGINI ET AL.	
	Examiner Shawquia Young	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/3/05, 6/16/05, 9/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-12 are currently pending in the instant application.

I. *Priority*

The instant application is a 371 of PCT/EP03/50982, filed on December 3, 2003 and claims benefit of Foreign Application ITALY MI2002A002658, filed on December 17, 2002.

II. *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on June 3, 2005, June 16, 2005 and September 22, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner. See Applicants' PTO-1449 form.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election without traverse of species 1-[4-(nitrooxymethyl) benzoylaminomethyl]-cyclohexaneacetic acid in the reply filed on March 16, 2007 is acknowledged. The Examiner has grouped Applicants' elected species in the group drawn to a compound of formula (I) wherein, c0 is 1; b0 is 0; k0 is 0; R is the radical of an analgesic drug for chronic pain of formula II; W is carbon; m is 1; R₀ is -(CH₂)_n-COOR_y; R_y is as defined in claim 1; n is an integer of from 0 to 2; R₁ is H; R₂ is as defined in claim 1; Q is as defined in claim 1; R_{1c} is H; C is -T_c-Y; T_c is (CO); Y is an alkylenoxy group -R'O-; R' is straight or branched C₁₋₂₀ alkenyl or a cycloalkylene

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without heteroatoms; n_X is an integer of from 0 to 5; R_{TIX} and R_{TIX'} are as defined in claim 1.

Subject matter not encompassed by the above group are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

IV. Rejections

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The term "derivatives" of the compounds of Claims 1-10 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1-10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "having the following

general formula" or "having the formula" renders the products indefinite as the phrase "having the following general formula" or "having the formula" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the compounds of the formula I that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the phrase "having the following general formula" or "having the formula" to read "of the formula" in claims 1-10.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-10 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 1-10 are drawn to "Nitrooxyderivatives or salts thereof of the general formula I." However, the "derivative" of the compounds of Claims 1-10 are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

V. *Objections*****

Claim Objection-Non Elected Subject Matter

Claims 1-10 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

Claim Objections

Claims 1, 2 and 6 are objected to because of the following informalities: In claim 1, c0 does not appear in the structure of formula I; the term "or" is missing in after the group cycloalkyl in variable R₅ and "or" is missing after the group "phenyl" in variable R₅; the term "or" is missing after the group guanidino in variable Q; and an extra period is after the group thioguanidino. In claim 2, the number "25" is after the word term "selected" and claim 2 does not end with a period. Each claim begins with a capital letter and ends with a period (MPEP 608.01 (m)). In claim 6, the last two compounds have the same structures, the term "and" is missing between the last two compounds and the claim does not end with a period. Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: the specification does not end with a period.

Appropriate correction is required.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

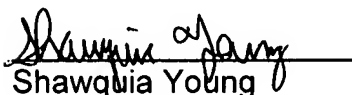
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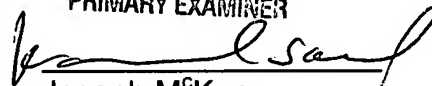
VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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